the current production year, the payment rate is 80 percent of the monthly payment rate calculated in paragraph (e) of this section.

(g) The monthly feed cost for covered livestock equals the product obtained by multiplying:

(1) 30 days;

(2) A payment quantity equal to the amount referred to in paragraph (h) of this section as the ''feed grain equivalent'', as determined under paragraph (h) of this section; and

(3) A payment rate equal to the corn price per pound, as determined in paragraph (i) of this section.

(h) The feed grain equivalent equals, in the case of:

(1) An adult beef cow, 15.7 pounds of corn per day or

(2) In the case of any other type or weight of covered livestock, an amount determined by the Secretary that represents the average number of pounds of corn per day necessary to feed that specific type of livestock.

(i) The corn price per pound equals the quotient obtained by dividing:

(1) The higher of:

(i) The national average corn price per bushel for the 12-month period immediately preceding March 1 of the calendar year for which LFP payment is calculated or

(ii) The national average corn price per bushel for the 24-month period immediately preceding March 1 of the calendar year for which LFP payment is calculated

(2) By 56.

(j) The monthly feed cost using the normal carrying capacity of the eligible grazing land equals the product obtained by multiplying:

(1) 30 days;

(2) A payment quantity equal to the feed grain equivalent of 15.7 pounds of corn per day;

(3) A payment rate equal to the corn price per pound, as determined in paragraph (i) of this section; and

(4) The number of animal units the eligible livestock producer's grazing land or pastureland can sustain during the normal grazing period in the county for the specific type of grazing land or pastureland, in the absence of a drought or fire, determined by dividing the:

(i) Number of eligible grazing land or pastureland acres of the specific type of grazing land or pastureland by

(ii) The normal carrying capacity of the specific type of eligible grazing land or pastureland as determined under this subpart.

(k) An eligible livestock producer will be eligible to receive payments for grazing losses due to a fire as specified in § 760.305(c):

(1) For the period, subject to paragraph (l)(2) of this section:

(i) Beginning on the date on which the Federal Agency prohibits the eligible livestock producer from using the managed rangeland for grazing and

(ii) Ending on the earlier of the last day of the Federal lease of the eligible livestock producer or the day that would make the period a 180 day period and

(2) For grazing losses that occur on not more than 180 days per calendar year.

(3) For 50 percent of the monthly feed cost, as determined under § 760.308(g), pro-rated to a daily rate, for the total number of livestock covered by the Federal lease of the eligible livestock producer.

Signed in Washington, DC, September 4, 2009.

Jonathan W. Coppess,

Administrator, Farm Service Agency.

[FR Doc. E9–21906 Filed 9–9–09; 11:15 am]

BILLING CODE 3410–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0352; FRL–8430–4]

Saflufenacil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of saflufenacil and its metabolites and degradates in or on various plant and livestock commodities. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 11, 2009. Objections and requests for hearings must be received on or before November 10, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0352. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–1243; e-mail address: *montague.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance

regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0352 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before November 10, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2008–0352, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of June 13, 2008 (73 FR 33814) (FRL–8367–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7322) by BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709–3528. The petition requested that 40 CFR part 180 be amended by adding a section for the herbicide saflufenacil and establishing tolerances therein for combined residues of saflufenacil (aka BAS 800 H), N′-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)benzyl]-*N*-isopropyl-*N*-methylsulfamide plus its metabolite M800H11, *N*-[2-chloro-5-(2,6-dioxo-4(trifluormethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-N′-isopropylsulfamide, and its metabolite M800H35, (*N*-[4-chloro-2-fluoro-5-({[(isopropylamino)sulfonyl]amino} carbonyl)phenyl]urea), in or on legume vegetables (group 06), citrus fruits (group 10), pome fruits (group 11), stone fruits (group 12), tree nuts (group 14), pistachio, cereal grains (group 15), undelinted cotton seed, cotton gin byproducts, and grape at 0.03 parts per million (ppm); foliage of legume vegetables (group 07); forage, fodder and straw of cereal grains (group 16); and sorghum stover at 0.1 ppm; almond hulls at 0.2 ppm; and sunflower seed at 0.7 ppm. The petition also requested that tolerances be established for residues of saflufenacil, M800H11 and M800H35 on animal kidney at 0.02 ppm and animal liver at 0.8 ppm, although the proposed tolerance levels for kidney and liver were not specified in the company's notice of filing. That notice referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has revised the tolerance levels for almond hulls and sunflower seed; determined that a tolerance for sorghum stover is unnecessary; determined that tolerances are required for additional livestock commodities; and revised the tolerance expression for plant and livestock commodities. EPA also revised commodity terms, as necessary, to agree with the Agency's Food and Feed Commodity Vocabulary. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of saflufenacil, including its metabolites and degradates, on the plant commodities almond, hulls at 0.10 ppm; cotton, gin byproducts at 0.10 ppm; cotton, undelinted seed at 0.03 ppm; fruit, citrus, group 10 at 0.03 ppm; fruit, pome, group 11 at 0.03 ppm; fruit, stone, group 12 at 0.03 ppm; grain, cereal, forage, fodder and straw group 16 at 0.10 ppm; grain, cereal, group 15 at 0.03 ppm; grape at 0.03 ppm; nut, tree, group 14 at 0.03 ppm; pistachio at 0.03 ppm; sunflower, seed at 1.0 ppm; vegetable, foliage of legume, group 7 at 0.10 ppm; and vegetable, legume, group 6 at 0.03 ppm; and on the livestock commodities cattle, fat at 0.01 ppm; cattle, liver at 0.80 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts, except liver at 0.02 ppm; goat, fat at 0.01 ppm; goat, liver at 0.80 ppm; goat, meat at 0.01 ppm; goat, meat byproducts, except liver at 0.02 ppm; hog, fat at 0.01 ppm; hog, liver at 0.80 ppm; hog, meat at 0.01 ppm; hog, meat byproducts, except liver at 0.02 ppm; horse, fat at 0.01 ppm; horse, liver at 0.80 ppm; horse, meat at 0.01 ppm; horse, meat byproducts, except liver at 0.02 ppm; milk at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, liver at 0.80 ppm; sheep, meat at 0.01 ppm; and sheep, meat byproducts, except liver at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Saflufenacil has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is slightly irritating to the eye but is neither a dermal irritant nor sensitizer.

Short-term, subchronic, and chronic toxicity studies in rats, mice, and dogs identified the hematopoietic system as the target organ of saflufenacil. Protoporphyrinogen oxidase inhibition in the mammalian species may result in disruption of heme synthesis which in turn causes anemia. In these studies, decreased hematological parameters (red blood cells (RBC), hematocrit (Ht), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC)) were seen at about the same dose level across species, except in the case of the dog, where the effects were seen at a slightly higher dose. These effects occurred around the same dose level from the short-term through long-term exposures without increasing in severity. Effects were also seen in the liver (increased weight, centrilobular fatty change, and lymphoid infiltrate) in mice, the spleen (increased spleen weight and extramedullary hematopoiesis) in rats, and in both these organs (increased iron storage in the liver and extramedullary hematopoiesis in the spleen) in dogs. These effects also occurred around the same dose level from the short-term through long-term exposures without increasing in severity. No dermal toxicity was seen at the limit dose in a 28–day dermal toxicity study in rats.

Carcinogenicity studies in rats and mice showed no evidence of increased incidence of tumors at the tested doses. Saflufenacil is weakly clastogenic in the *in vitro* chromosomal aberration assay in V79 cells in the presence of S9 activation; however, the response was not evident in the absence of S9 activation. It is neither mutagenic in bacterial cells nor clastogenic in rodents *in vivo*. Saflufenacil is classified as ''not likely to be carcinogenic to humans.''

Increased fetal and offspring susceptibility to saflufenacil were observed in the developmental toxicity studies in the rat and rabbit and in the 2–generation reproduction study in the rat. Developmental effects such as decreased fetal body weights and increased skeletal variations occurred at doses that were not maternally toxic in the developmental study in rats, indicating increased quantitative susceptibility. In rabbits, developmental effects such as increased liver porphyrins were observed at doses that were not maternally toxic, indicating increased quantitative susceptibility. In the 2–generation reproduction study in rats, offspring effects such as increased number of stillborn pups, decreased viability and lactation indices, decreased pre-weaning body weight and/or body-weight gain, and changes in hematological parameters were observed at a dose resulting in less severe maternal toxicity (decreased food intake, body weight/weight gain and changes in hematological parameters and organ weights indicative of anemia), indicating increased qualitative susceptibility.

There was no evidence of neurotoxicity or neuropathology in the toxicity database for saflufenacil. In the acute neurotoxicity study, a decrease in motor activity was observed on the first day of dosing at the limit dose in males only. The finding was not accompanied by any other neuropathological changes and was considered a reflection of a mild and transient general systemic toxicity and not a substance-specific neurotoxic effect. In the subchronic neurotoxicity study, systemic toxicity (anemia), but no evidence of neurotoxicity, was seen in males and females.

There is no evidence of immunotoxity in the saflufenacil database. The increase in spleen weight seen only in rats in the 90–day oral toxicity study is attributable to an increased clearance of defective RBCs (i.e., defective hemoglobin synthesis) and is thus an indication of toxicity to the hematopoietic system rather than to the immune system.

Specific information on the studies received and the nature of the adverse effects caused by saflufenacil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document *Saflufenacil. Revised Human-Health Risk Assessment for Proposed Uses in/on Legume Vegetables (Crop Group 06), the Foliage of Legume Vegetables (Crop Group 07), Citrus Fruits (Crop Group 10), Pome Fruits (Crop Group 11), Stone Fruits (Crop Group 12), Tree Nuts (Crop Group14), Cereal Grains (Crop Group 15), Forage, Fodder and Straw of Cereal Grains (Crop Group 16), Grapes, Cotton, and Sunflower*, page 45 in docket ID number EPA–HQ–OPP–2008–0352.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for saflufenacil used for human risk assessment can be found at *http://www.regulations.gov* in the document *Saflufenacil. Revised Human-Health Risk Assessment for Proposed Uses in/on Legume Vegetables (Crop Group 06), the Foliage of Legume Vegetables (Crop Group 07), Citrus Fruits (Crop Group 10), Pome Fruits (Crop Group 11), Stone Fruits (Crop Group 12), Tree Nuts (Crop Group14), Cereal Grains (Crop Group 15), Forage, Fodder and Straw of Cereal Grains*

(Crop Group 16), Grapes, Cotton, and Sunflower, page 27 in docket ID number EPA–HQ–OPP–2008–0352.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to saflufenacil, EPA considered exposure under the petitioned-for tolerances. No other tolerances have been established for saflufenacil. EPA assessed dietary exposures from saflufenacil in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure.

In estimating acute dietary exposure, EPA used food consumption information from the U. S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of commodities are treated with saflufenacil. Dietary Exposure Evaluation Model (DEEM(TM)) 7.81 default concentration factors were used to estimate residues of saflufenacil in processed commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used the same assumptions (tolerance-level residues, 100% crop treated, and DEEM(TM) 7.81 default concentration factors) as in the acute exposure assessment.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice, EPA classified saflufenacil as ''not likely to be carcinogenic to humans;'' therefore, an exposure assessment to evaluate cancer risk is unnecessary for this chemical.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue or PCT information in the dietary assessment for saflufenacil. Tolerance-level residues and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for saflufenacil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of saflufenacil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model/Ground Water (PRZM/GW) models, the estimated drinking water concentrations (EDWCs) of saflufenacil for acute exposures are estimated to be 37.3 parts per billion (ppb) for surface water and 180 ppb for ground water. EDWCs for chronic exposures for non-cancer assessments are estimated to be 23.8 ppb for surface water and 173 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 180 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 173 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Saflufenacil is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found saflufenacil to share a common mechanism of toxicity with any other substances, and saflufenacil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that saflufenacil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicity database for saflufenacil includes rat and rabbit developmental toxicity studies and a two-generation reproduction toxicity study in rats. As discussed in Unit III.A. there was evidence of quantitative susceptibility of fetuses to saflufenacil exposure in the developmental toxicity studies in rats and rabbits and evidence of qualitative susceptibility of offspring in the rat reproduction study.

An analysis was performed to determine the degree of concern for the effects observed in the developmental and reproduction toxicity studies when considered in the context of all available toxicity data, and to identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of saflufenacil. The degree of concern is low and there are no residual uncertainties for the increased susceptibility since:

i. Clear NOAELs/LOAELs were established for the developmental effects seen in rats and rabbits as well as for the offspring effects seen in the 2–generation reproduction study.

ii. Dose-response relationships for the effects of concern are well characterized.

iii. None of the effects in the developmental or reproduction studies were attributable to a single exposure and, therefore, are not of concern for acute risk assessment.

iv. The dose used to evaluate chronic dietary risks (4.6 milligrams/kilogram/day (mg/kg/day)) is lower than the NOAELS for fetal/offspring effects in the developmental and reproduction studies (5 mg/kg/day in the rat developmental study, 50 mg/kg/day in the rabbit developmental study, and 15 mg/kg/day in the rat reproduction study) and is, therefore, protective of the developmental and offspring effects observed in these studies and

v. Residential exposures are not expected, since there are no residential uses proposed for saflufenacil.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for saflufenacil is adequate to assess the prenatal and postnatal toxicity of saflufenacil. In accordance with 40 CFR part 158 Toxicology Data requirements, an immunotoxicity study (870.7800) is required for saflufenacil. In the absence of specific immunotoxicity studies, EPA has evaluated the available saflufenacil toxicity data to determine whether an additional database uncertainty factor is needed to account for potential immunotoxicity. An increase in spleen weight, an organ of the immune system, was seen in rats in the 90–day oral toxicity study. This effect is attributable to an increased clearance of defective RBCs (i.e, defective hemoglobin synthesis) and is thus an indication of toxicity to the hematopoietic system rather than to the immune system. There were no other effects on immune system organs observed in toxicity studies with saflufenacil, and saflufenacil does not belong to a class of chemicals (e.g., the organotins, heavy metals, or halogenated aromatic hydrocarbons) that would be expected to be immunotoxic. Based on these considerations, EPA does not believe that conducting immunotoxicity testing will result in a point of departure lower than those already selected for saflufenacil, and an additional database uncertainty factor is not needed to account for potential immunotoxicity.

ii. There is no indication that saflufenacil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is evidence of increased quantitative and qualitative susceptibility of offspring in the developmental and reproduction studies for saflufenacil; however, the degree of concern is low and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of saflufenacil.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the groundwater and surface water modeling used to assess exposure to saflufenacil in drinking water. Residential exposure to saflufenacil is not expected. These assessments will not underestimate the exposure and risks posed by saflufenacil.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk*. An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to saflufenacil will occupy less than 1% of the aPAD for all population subgroups, including infants and children.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to saflufenacil from food and water will utilize 28% of the cPAD for infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for saflufenacil.

3. *Short-term/intermediate-term risk*. Short-term and intermediate-term aggregate exposures take into account short-term or intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Saflufenacil is not registered for any use patterns that would result in residential exposure. Therefore, the short-term and intermediate-term aggregate risk is the sum of the risk from exposure to saflufenacil through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. Saflufenacil is classified as ''not likely to be carcinogenic to humans'' and is, therefore, not expected to pose a cancer risk.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to saflufenacil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry (LC-MS/MS) methods D0603/02 (plants) and L0073/01 (livestock)) is available to enforce the tolerance expression. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

B. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) established for residues of saflufenacil and its metabolites in crops or livestock commodities. The residue definition and tolerances being established by this rule are harmonized with MRLs being established concurrently by Canada and Australia.

C. Response to Comments

EPA received one comment in response to the petition notice of filing. The commenter, a private citizen, expressed strong objections to ''genetically engineered foods.'' The commenter's objections are not relevant to this petition, since the tolerances for saflufenacil do not involve genetically altered herbicide-tolerant crops.

D. Revisions to Petitioned-For Tolerances

Based upon review of the data supporting the petition, EPA has revised the tolerance levels for almond hulls and sunflower seed; determined that a tolerance for sorghum stover is unnecessary; determined that tolerances are required for additional livestock commodities; and revised the tolerance expression for plant and livestock commodities. EPA also revised commodity terms, as necessary, to agree with the Agency's Food and Feed Commodity Vocabulary.

EPA increased the tolerance on sunflower seed from 0.7 ppm to 1.0 ppm based on analysis of the field trial data using the Agency's Tolerance Spreadsheet in accordance with the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*. The tolerance on almond hulls was decreased from 0.2 ppm to 0.10 ppm, based on the results of field trials showing that all residues were less than the limit of quantitation (LOQ) (0.025 ppm for each analyte) at the proposed preharvest interval (PHI) of 7 days. The

tolerance level was determined by adding the LOQs for saflufenacil and its two regulated analytes and rounding up to 0.10 ppm. EPA determined that a separate tolerance on sorghum stover is unnecessary, since sorghum stover is included in crop group 16 (grain, cereal, forage, fodder and straw group).

The petitioner proposed tolerances for saflufenacil and its metabolites M800H11 and M800H35 on animal kidney at 0.02 ppm and on animal liver at 0.80 ppm. EPA determined that M800H11 and M800H35 should be excluded from the tolerance expression for livestock commodities based on the low potential for exposure to these metabolites from the proposed uses. Data from the cattle feeding study with saflufenacil indicate that tolerances are needed for residues of saflufenacil at 0.80 ppm in liver and at 0.02 ppm in the meat byproducts, except liver, of cattle, goats, horses, hogs, and sheep. EPA is also establishing tolerances at the method LOQ (0.01 ppm) for fat, meat, and milk, because feeding levels in the cattle feeding study were not high enough (i.e., 10X) to demonstrate conclusively that detectable residues would not occur in these livestock commodities.

Although the commodity terms proposed in the petition itself were largely in accordance with the Agency's Food and Feed Commodity Vocabulary, many were incorrectly specified in the Notice of Filing: legume vegetables (group 06); citrus fruits (group 10); pome fruits (group 11); stone fruits (group 12); tree nuts (group 14); cereal grains (group 15); undelinted cotton seed; cotton gin byproducts; foliage of legume vegetables (group 07); forage, fodder and straw of cereal grains (group 16); almond hulls; and sunflower seed. EPA has corrected these commodity terms to read: vegetable, legume, group 6; fruit, citrus, group 10; fruit, pome, group 11; fruit, stone, group 12; nut, tree, group 14; grain, cereal, group 15; cotton, undelinted seed; cotton, gin byproducts; vegetable, foliage of legume, group 7; grain, cereal, forage, fodder and straw group 16; almond, hulls; and sunflower, seed.

Finally, EPA is revising the tolerance expressions for plant and livestock commodities to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expressions make clear that the tolerances cover ''residues of saflufenacil, including its metabolites and degradates,'' and that compliance with the tolerance levels will be determined, for livestock commodities, by measuring only saflufenacil; and for plant commodities, by measuring only the sum of saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino] sulfonyl]benzamide, and its metabolites *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-*N'*-isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-({[[(isopropylamino)sulfonyl] amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil.

V. Conclusion

Therefore, tolerances are established for residues of saflufenacil, including its metabolites and degradates, on the plant commodities almond, hulls at 0.10 ppm; cotton, gin byproducts at 0.10 ppm; cotton, undelinted seed at 0.03 ppm; fruit, citrus, group 10 at 0.03 ppm; fruit, pome, group 11 at 0.03 ppm; fruit, stone, group 12 at 0.03 ppm; grain, cereal, forage, fodder and straw group 16 at 0.10 ppm; grain, cereal, group 15 at 0.03 ppm; grape at 0.03 ppm; nut, tree, group 14 at 0.03 ppm; pistachio at 0.03 ppm; sunflower, seed at 1.0 ppm; vegetable, foliage of legume, group 7 at 0.10 ppm; and vegetable, legume, group 6 at 0.03 ppm; and on the livestock commodities cattle, fat at 0.01 ppm; cattle, liver at 0.80 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts, except liver at 0.02 ppm; goat, fat at 0.01 ppm; goat, liver at 0.80 ppm; goat, meat at 0.01 ppm; goat, meat byproducts, except liver at 0.02 ppm; hog, fat at 0.01 ppm; hog, liver at 0.80 ppm; hog, meat at 0.01 ppm; hog, meat byproducts, except liver at 0.02 ppm; horse, fat at 0.01 ppm; horse, liver at 0.80 ppm; horse, meat at 0.01 ppm; horse, meat byproducts, except liver at 0.02 ppm; milk at 0.01 ppm; sheep, fat at 0.01 ppm; sheep, liver at 0.80 ppm; sheep, meat at 0.01 ppm; and sheep, meat byproducts, except liver at 0.02 ppm. Compliance with the tolerance levels for plant commodities will be determined by measuring only the sum of saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl) amino]sulfonyl]benzamide, and its metabolites *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-*N'*-isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino) sulfonyl]amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil. Compliance with the tolerance levels for livestock commodities will be determined by measuring only saflufenacil.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the

Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 2, 2009.

Debra Edwards,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.649 is added to read as follows:

§ 180.649 Saflufenacil; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of saflufenacil, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino] sulfonyl]benzamide, and its metabolites *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-*N*′-isopropylsulfamide and fluoro-5-({[(isopropylamino)sulfonyl] amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil, in or on the commodities.

Commodity	Parts per million
Almond, hulls	0.10
Cotton, gin byproducts	0.10
Cotton, undelinted seed	0.03
Fruit, citrus, group 10	0.03
Fruit, pome, group 11	0.03
Fruit, stone, group 12	0.03
Grain, cereal, forage, fodder and straw Group 16	0.10
Grain, cereal, group 15	0.03
Grape	0.03
Nut, tree, group 14	0.03
Pistachio	0.03
Sunflower, seed	1.0
Vegetable, foliage of legume, group 7	0.10
Vegetable, legume, group 6	0.03

(2) Tolerances are established for residues of saflufenacil, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl) amino]sulfonyl]benzamide, in or on the commodities.

Commodity	Parts per million
Cattle, fat	0.01
Cattle, liver	0.80
Cattle, meat	0.01
Cattle, meat byproducts, except liver	0.02
Goat, fat	0.01
Goat, liver	0.80
Goat, meat	0.01
Goat, meat byproducts, except liver	0.02
Hog, fat	0.01
Hog, liver	0.80
Hog, meat	0.01
Hog, meat byproducts, except liver	0.02
Horse, fat	0.01
Horse, liver	0.80
Horse, meat	0.01
Horse, meat byproducts, except liver	0.02
Milk	0.01
Sheep, fat	0.01
Sheep, liver	0.80
Sheep, meat	0.01
Sheep, meat byproducts, except liver	0.02

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. E9–21826 Filed 9–10–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0834; FRL–8426–2]

Azinphos-methyl, Disulfoton, Esfenvalerate, Ethylene oxide, Fenvalerate, et al.; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking certain tolerances for the fungicides prothioconazole and thiabendazole; the herbicide primisulfuron-methyl; and the insecticides azinphos-methyl, disulfoton, esfenvalerate, fenvalerate, and phosalone; the plant growth regulator 1-naphthaleneacetic acid; and the antimicrobial/insecticidal agent ethylene oxide. Also, EPA is modifying certain tolerances for the insecticides disulfoton, esfenvalerate, and phosmet; and the plant growth regulator 1-naphthaleneacetic. In addition, EPA is establishing new tolerances for the insecticides disulfoton, esfenvalerate, and phosmet; and the antimicrobial/insecticidal agent ethylene oxide and ethylene chlorohydrin (a reaction product formed during the fumigation/sterilization process). The regulatory actions finalized in this document are in follow-up to the Agency's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and tolerance reassessment program under the Federal Food, Drug, and Cosmetic Act (FFDCA), section 408(q).

DATES: This regulation is effective September 11, 2009. Objections and requests for hearings must be received on or before November 10, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0834. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.